CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 DOVER, DELAWARE 19904-2467 **STATE OF DELAWARE**BOARD OF PHARMACY

TELEPHONE: (302) 744-4500 FAX: (302) 739-2711 WEBSITE: <u>DPR.DELAWARE.GOV</u> EMAIL: <u>customerservice.dpr@state.de.us</u>



PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, November 19, 2014 9:30 am

PLACE: Conference Room A, 2nd Floor Cannon Building

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: January 21, 2015

MEMBERS PRESENT

Kenneth Sellers, Public Member, President Susan Esposito, R.Ph., Professional Member, Vice President Kimberly Robbins, R.Ph., Professional Member Bonnie Wallner, R.Ph., Professional Member Joli Martini, R.Ph., Professional Member Tejal Patel, PharmD, Professional Member Hooshang Shanehsaz, R.Ph., Professional Member Jay Galloway, Public Member

MEMBERS ABSENT

None

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David W. Dryden, R.Ph., J.D., Executive Secretary Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Jaime Frink
Suzanne Raab-Long
Don Holst
Jay Patel
Charlotte Lopacki
Stephen Maylie
Nancy Sawyer
Ann Campagna
Matt VenDovern
Janis Levit
Jill Spivey
Tiffany Sorey
Cheryl Heiks

Jinesh Mukundan

CALL TO ORDER

Mr. Sellers called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Martini, seconded by Ms. Patel, to approve the meeting minutes for October 15, 2014 as amended. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Seller's welcomed Hooshang Shanehsaz to the board. Mr. Sellers began with a discussion regarding robbery and the safe guards in place to help protect and prevent stolen drugs. Mr. Dryden stated that pharmacies are provided with guidance to follow after a robbery has occurred as well as guidelines on requirements and specifications of safes to be housed within the pharmacy. The board discussed current policies and procedures in place at their respective locations and provided feedback regarding Mr. Seller's concerns.

Mr. Seller's appointed Tejal Patel to replace Sandy Robinson on the following committees: Nursing Joint Practice Committee (prescriptive authority), and the Medical Physician Assistant Committee (prescriptive authority). Ms. Patel accepted the appointments.

UNFINISHED BUSINESS

Complaint Status

- 13-03-11 Assigned to Hearing Officer
- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Forwarded to Office of Attorney General
- 13-19-11 Forwarded to Office of Attorney General
- 13-09-12 Assigned
- 13-01-13 Forwarded to Office of Attorney General
- 13-02-13 Assigned
- 13-03-13 Assigned
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Assigned
- 13-06-13 Forwarded to Office of Attorney General
- 13-07-13 Assigned
- 13-08-13 Assigned
- 13-09-13 Assigned
- 13-11-13 Forwarded to Office of Attorney General
- 13-13-13 Forwarded to Office of Attorney General
- 13-14-13 Assigned
- 13-15-13 Assigned
- 13-16-13 Assigned
- 13-17-13 Assigned
- 13-18-13 Assigned
- 13-19-13 Assigned
- 13-20-13 Assigned
- 13-21-13 Assigned
- 13-22-13 Assigned
- 13-23-13 Assigned
- 13-24-13 Assigned

Re-Review of Proposal to Deny

None

Proposal to Deny Hearing

Concierge Compounding was scheduled for a hearing to propose to deny their application @ 9:40 am. The hearing was held as scheduled. A motion was made by Ms. Martini, seconded by Mr. Galloway to approve the application, Ms. Esposito and Ms. Robbins opposed. The motion carried.

Re-Review of Tabled Applications

None

Final Denal of Application

None

Review of Practitioner/Pharmacy Ownership

No Report

Re-Review of CPR Course - Emergency University, Ca.

Mr. Galloway reported that he had been in contact with Emergency University and there are online courses available with skills review via video feed. The board discussed online versus hands on feedback received from peers. The board made a motion to amend the rules and regulations to add "Hands on Curriculum" to regulation 14.1.1 the motion was made by Ms. Martini, seconded by Ms. Esposito. The motion carried unanimously. The board Deputy Attorney General Eileen Kelly will draft the proposed changes for review during the next scheduled meeting.

DEA Federal Rules for Disposal

Mr. Dryden presented the board with the federal guidelines regarding disposal. The board reviewed the guidelines and a motion was made by Ms. Esposito seconded by Mr. Galloway to add regulation 5.1.14.3 addressing disposal. The motion unanimously carried.

NEW BUSINESS

Mr. Sellers read into the record the following ratifications.

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist: A1-0004694 Dawit M. Yifru

A1-0004695 Maria Jeanne Lanser A1-0004696 Marx A. Twumasi

A1-0004697 Duncan Joseph Runyon

A1-0004698 Erika N. Bronk A1-0004699 Jae Hyun Park

A1-0004700 Tovonnia Wachet Collins

A1-0004701 Uday J. Gohel A1-0004702 Sally M. Abbonizio A1-0004703 Jennifer M. Demeno

A motion was made by Ms. Martini, seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern: A7-0002379 Ryan Scott Greenley

A motion was made by Ms. Martini, seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001526 VIP Pet Meds, Inc

A9-0001527 Precision Rx Compounding LLC A9-0001528 North Beaches Pharmacy, Inc.

A9-0001529 Walgreen Pharmacy Services Midwest, LLC

> A9-0001530 1st Choice Pharmacy, LLC North Huntingdon Medical Inc. dba Norwin Pharmacy A9-0001531 A9-0001532 Estonna Management, LLC A9-0001533 PSG of Sarasota, LLC A9-0001534 InnovativeRx Gulf Coast Pharmacy, Inc. A9-0001535 Executive Pharmacy A9-0001536 Marian Respiratory Care, Inc. A9-0001537 Walgreen Pharmacy Services Midwest, LLC A9-0001538 Millennium Pharmacy Systems, Inc. Blair Pharmacy, Inc. A9-0001539 A9-0001540 Pine Pharmaceuticals LLC Physician Specialty Pharmacy A9-0001541 A9-0001542 Kaba Fusion, Inc.

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001499 Dubin Medical, Inc
A4-0002123 Bausch and Lomb, Inc.
A4-0002125 Bausch and Lomb, Inc.
A4-0002126 McKesson Medical-Surgical Inc.
A4-0002127 WellGistics, LLC
A4-0002128 Eq Detroit, Inc.
A4-0002129 Tolmar Pharmaceuticals, Inc.
A4-0002130 Tolmar Pharmaceutical Group, Inc.
A4-0002131 DMS Pharmaceutical Group, Inc.
A4-0002132 Medi-Nuclear, LLC
A4-0002133 Prescript Pharmaceuticals, Inc.
A4-0002134 Smith Medical Partners, LLC
A4-0002135 BMTM Services, Inc.
A4-0002136 MWI Veterinary Supply Co, dba IVESCO

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000112 Home MediService, Inc. A2-0000113 Verus Healthcare, LLC

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000650 Target Store T-1146

A3-0000975 Delaware CVS Pharmacy, LLC #10375 A3-0000976 Delaware CVS Pharmacy, L.L.C. #3231

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

AA-0000001 Edge Pharmacy Services, LLC AA-0000002 Pine Pharmaceuticals LLC

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted a PIC interviews with:

Jinesh Mukundan, ShopRite Pharmacy #589 Wilmington, De.

Stephen Maylie, Target #1146 Brandywine, De

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the amending the agenda to add: Jay Patel for PIC Interview. The motion unanimously carried.

Jay Patel, Walgreens #11011

Consultant Pharmacist Interviews

Charlotte Lopacki, New Castle Pharmacy

Board Review and Consideration of Consent Agreement

None

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Facility: Millennium Pharmacy Systems, a motion was made by Ms. Robbins, seconded by Ms. Esposito to approve the application. The motion carried.

Facility: Medline Industries, Inc., a motion was made by Ms. Martini, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Facility: Genoa Healthcare of New Jersey, a motion was made by Ms. Esposito, seconded by Ms. Martini, to approve the application. The motion unanimously carried.

Facility: DermaTran Health Solutions, a motion was made by Ms. Robbins, seconded by Ms. Martini, to approve the application. The motion unanimously carried.

Facility: Factor Support Network Pharmacy, a motion was made by s. Martini, seconded by Ms. Robbins, to approve the application. The motion unanimously carried.

Facility: Hi-Tech Pharmacal Co., a motion was made by Ms. Robbins, seconded by Ms. Martini, to approve the application. The motion unanimously carried.

Facility: Bound Tree Medical, a motion was made by Ms. Esposito, seconded by Ms. Martini, to approve the application. The motion unanimously carried.

Facility: Smith Medical ASD, a motion was made by Ms. Martini, seconded by Ms. Esposito to approve the application. The motion carried.

Facility: Asclemed dba: Enovachem Manufacturing, a motion was made by Ms. Robbins, seconded by Ms. Martini to approve the application. The motion carried.

Facility: Par Sterile Manufacturing, a motion was made by Ms. Robbins, seconded by Ms. Esposito to table the application. The motion carried.

Review Request for Termination of Probation

Paul O Ojewoye petitioned the board requesting the lifting of his probation per his board order; a motion was made by Ms. Martini, seconded by Ms. Esposito to approve the request. The motion carried.

CE Approval Requests

NASCA Conference 13.75 CE requested by David Dryden, Michelle McCreary, and Samantha Nettesheim, a motion was made by Ms. Esposito, seconded by Ms. Robbins to approve the request. The motion carried.

NABP Board Executive Meeting 5 CE requested by David Dryden a motion was made by Ms. Robbins, seconded by Ms. Patel to approve the request. The motion carried.

COMMITTEE REPORTS

Legislative - Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

Deputy Attorney General Eileen Kelly expressed concerns with current statute concerning disciplinary sanctions need to be broadened and updated to facilitate public protections. The board agreed to review these concerns, Ms. Kelly will present the board with proposed changes during the next scheduled meeting.

Continuing Education — Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs - Ken Sellers and Jay Galloway:

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

Ms. Patel attended the Delaware Pharmacy Society meeting held November 18, 2015. She updated the board regarding open positions at DPS and their upcoming schedule of events.

Controlled Substance Liaisons - Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

No Report

Prescription Safety Committee - This will be newly formed committee to address Transition of Care, Mandatory Consultation, and Electronic Pharmacy records. Mr. Sellers will determine during the next scheduled meeting who will be selected as committee members based on interest from members of the board and stake holders.

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden: Proposed Rules and Regulations changes, to be reviewed and discussed at the next scheduled meeting on January 21, 2015. Mr. Dryden will forward the USP 795/797 to the board for review prior to the meeting.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Susan Esposito and David Dryden:

Mr. Dryden presented the board with 2014 NABP Pharmacy Technician Survey licensure statistics for all states.

Collaborative Care Committee — Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:
No Report

BOARD CORRESPONDENCE

Mr. Dryden provided a handout from NABP, Proliferation of Rogue Online Drug Sellers Feeds Prescription Drug Abuse Epidemic for the board to review.

Mr. Dryden provided a handout from NABP .Pharmacy available for Delaware Board of Pharmacy for the board to review. Delaware will utilize this domain to assist with Delaware questions presented to NABP a motion was made to apply for the grant to have Delaware added to the NABP domain by Ms. Esposito, seconded by Ms. Robbins to move forward with the request. The motion carried.

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden informed the board of several off site meetings attend by key personnel from the division. Highlights of those meetings include: NABP will have a meeting to discuss national inspections of compounding pharmacies. We continue to have support from the Federal Food and Drug Administration conducting sterile compounding inspections for applications received in state. The Prescription Monitoring Program geo-mapping project with the University of Delaware is underway. Mr. Dryden alerted the board of several robberies that occurred within the last month. He stated all necessary reports and inspections after the robberies were completed. He also stated that internal theft issues are on the rise. These issues are typically handled internally at the pharmacy level which creates concern for public safety. Mr. Dryden stated internal theft issues will now be reported to the Delaware State Police. Controlled Substance Committee has been working on Safe Opioid prescribing document. Mr. Dryden will forward to the board for review. Naloxone endeavors are on the rise. The Controlled Substance committee has taken action against Dr. Patrick Titus, suspending his registration for 1 year followed by 3 years' probation. An alert was sent to all pharmacies, emergency care facilities and drug treatment facilities within the state to inform them of possible influx of patients to their facilities. Michelle McCreary has been working to update the PIC Self-Inspection form as well a newly created Hospital PIC self-inspection form. The new forms will be available online in January 2015. Mr. Dryden shared that increased focus will be placed on inspections and the complaint process in 2015.

NEWSLETTER UPDATES

No Report

OTHER BUSINESS BEFORE THE BOARD

Inactive Status clarification - keep on agenda for more discussion Eileen Kelly DAG will provide more information during the next meeting.

Mandatory Consultation by Community R.Ph. – Ms. McCreary reported that there are some challenges with schedule changes to drugs which increased counseling time for unnecessary consultations when actual prescribed drugs haven't changed. Counseling has played a key role in reducing medication errors. Some feedback provided from stake holders is this is too restrictive and impossible to adhere to in the normal course of business. The board determined that a "Prescription Safety Committee" should be formed to address this and other issues.

Legality of Pharmacies Providing Kickbacks to Prescribers in Exchange for Referrals – a letter was provided to the board for review during the meeting on November 19, 2014. The board would like to keep this on the agenda for more discussion.

PUBLIC COMMENT

Tiffany Surey, Pharmacist, expressed support of the hands on CPR training due to recent events that required her to use her training recently on 2 different occasions. She stated that had she not had the hands on interaction during her training she would not have felt confident enough in her abilities. She stated little items such as a song provided to her to keep the proper rhythm during compressions made a huge difference in her effectiveness during the event. She would recommend all CPR classes be hands on because of her experiences recently.

NEXT SCHEDULED MEETING

The next meeting is scheduled for January 21, 2015 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the board a motion to adjourn the meeting was made by Ms. Martini, seconded by Ms. Robbins at 12:26 pm.

Respectfully submitted,

Christine Mast

Administrative Specialist III